

C. Remarks

The claims are 48-61, 63-66, 73-77, 79 and 80, with claims x being independent. Claims 54-61 and 75-77 have been withdrawn from consideration by the Examiner as being drawn to non-elected subject matter. Claims 48-53, 63-66, 73, 74, 79 and 80 have been amended; specifically, claims 48 and 63 have been amended to remove the limitation regarding the provision of a vibratory stimulus, and the claims have generally been amended as to formal matters. Applicant submits that no new matter has been added. Reconsideration of the present claims is respectfully requested.

The Examiner has issued a Notice of Non-Responsive Amendment in this case in response to the Amendment filed on February 3, 2005. Specifically, the Examiner noted that the addition of limitations regarding the provision of a vibratory stimulus in each of claims 48 and 63 constituted an impermissible shift between elected subject matter and non-elected subject matter. In an effort to expedite prosecution, Applicant has now amended each of claims 48 and 63 to remove the limitation in question. In addition, Applicant has also provided further argumentation (see below) regarding the patentability of the claims as now amended over the cited art.

Claims 48 and 63 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ke (U.S. Patent No. 6,352,970). Applicant respectfully traverses this rejection.

The present invention (as now claimed in claims 48 and 63) is specifically directed to a method of promoting bone growth or new bone formation at a fracture site by administering a drug containing at least one bisphosphonate. Other embodiments of the

invention are directed to the administration of at least two bisphosphonates. Importantly, according to the methods of the present invention, an amount of at least one bisphosphonate effective to promote bone growth or new bone formation at a fracture site is administered to a subject with a fractured bone. This key feature is not disclosed or suggested in any way by the presently cited art (Ke).

Ke focuses on the use of leptin or a leptin mimetic (at times in combination with estrogen, a selective estrogen receptor modulator or a bisphosphonate) for treating low bone mass or bone fracture. Since Ke refers, in general, to the use of leptin alone for these purposes, one of ordinary skill in this art would not, upon reading Ke, have any reason to believe that a bisphosphonate on its own would be effective for the purposes set forth therein.

Moreover, Ke does not teach or suggest anywhere that bisphosphonates might be used for promoting bone growth or new bone formation at a fracture site. In fact, Ke explicitly teaches against such a notion. At column 2, lines 14-18, Ke states: “All approved therapies and clinically advanced candidates including . . . bisphosphonates . . . act to prevent bone loss by inhibiting bone resorption, but these agents cannot restore bone mass.” Given this disclosure, one of ordinary skill in the art would surely not be motivated to pursue a method of promoting bone growth or new bone formation which centered on the administration of a bisphosphonate.


In sum, it is clear that Ke does not render the presently claimed invention obvious. Ke simply fails to disclose or suggest certain key features of the present invention, namely the administration of an amount of at least one bisphosphonate which is

effective to promote bone growth or new bone formation at a fracture site. Accordingly, Applicant respectfully requests withdrawal of the §103 rejection.

In view of the foregoing amendments and remarks, favorable reconsideration and passage to issue of the present case is respectfully requested. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicant's undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



Elizabeth F. Holowacz
Attorney for Applicant
Registration No. 42,667

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

NY_MAIN 544284v1